

## **REMARKS**

### **Interview Summary**

Applicant wishes to thank the Examiner for considering the issues raised in the October 24 Office Action during the interview on February 22. During the interview, the Examiner and Applicant's attorney discussed cited prior art and claim amendments that would put the application in a condition for allowance. The claim amendments discussed in the interview are reflected above. The remainder of the substance of the interview is further reflected below. Applicant believes the application is now in a condition for allowance and appreciates the Examiner's due consideration of the amendments above and the following comments.

### **Objection to Claim 1**

The Examiner has objected that the language "wherein a first unattached margin whereby . . ." in claim 1 is unclear. In response, Applicant has made a minor change to the wording of claim 1 in an effort to make the claim more clear. Applicant respectfully submits that the meaning of claim 1, particularly in light of the amendment above, would be clear to those of skill in the art. As explained in the specification, and recited in the claims, the inner and outer graft layers 18, 20 are secured together at areas of attachment 22. (¶ [0019]). The "unattached margins 24 are formed between each of the attached areas 22 and the edges of the open areas 16 (i.e., the edges of the struts 14). Unlike the areas of attachment 22 where the inner and outer layers 18, 20 are secured together, the unattached margins 24 are areas where the inner and outer layers 18, 20 are not secured together." (¶ [0019]). These features are clearly shown in each of the figures of the application. Accordingly, in light of the claim amendment, and the foregoing explanation, the Examiner may withdraw this objection.

### **35 U.S.C. § 112 Claim Rejections**

The Examiner has rejected claim 7 as being indefinite under 35 U.S.C. § 112 ¶ 2 because the language "said first attached area extends peripherally all around said first attached area" is unclear. Applicant agrees with the Examiner's position and notes that the language referred to by the Examiner was a clerical error. In response, Applicant

has amended claim 7 to clarify that “said first unattached margin extends peripherally all around said first attached area.” Accordingly, the Examiner may now withdraw this rejection.

### **Prior Art Rejections**

The Examiner has rejected claims 1-3 as being anticipated under 35 U.S.C. § 102(b) by Kuwahara et al. (U.S. Patent No. 6,346,119). The Examiner has also rejected claims 1-11, 13-14 and 16-19 as being anticipated under 35 U.S.C. § 102(b) by Lentz et al. (U.S. Patent No. 5,843,166). The Examiner has also rejected claims 15 and 24-34 as being unpatentable under 35 U.S.C. § 103(a) over Lentz in view of Buirge et al. (U.S. Patent Pub. No. 2001/0034550). The Examiner has also rejected claim 12 as being unpatentable under 35 U.S.C. § 103(a) over Lentz in view of Lombardi et al. (U.S. Patent No. 6,579,314). The Examiner has also rejected claims 20-23 as being unpatentable under 35 U.S.C. § 103(a) over Lentz in view of Buirge and in further view of Lombardi.

Applicant has carefully considered the Examiner's comments. In response, Applicant has amended claim 1 and 28 and has added new claims 35 and 36. Applicant respectfully submits that the prior art of record does not disclose all of the limitations of Applicant's claims as now presented. Moreover, there is no suggestion or motivation to combine the prior art to achieve Applicant's claimed inventions.

Referring to claims 1-27, the Examiner argues that Kuwahara and Lentz both independently disclose all of the limitations of independent claim 1. However, Applicant respectfully submits that neither of these references disclose all of the limitations of claim 1 as now presented. In particular, Kuwahara does not disclose unattached margins that are on the same side of the attached areas to allow the graft layers to move relative to the stent. This feature of the invention is described in Applicant's specification in paragraph [0020]. This limitation is not disclosed in Kuwahara. In Kuwahara, an inner and outer layer are adhered together with a polyester resin. However, as shown in Figure 2 of Kuwahara and described in the specification thereof, the areas of attachment abut opposite sides of the zig-zag stent structure. (Col. 5, lines 19-23; col. 6, lines 23-28; col. 7, lines 9-14). Specifically, the attached areas are positioned within the apices of the zig-zag structure at the top and bottom portions of

the stent. As a result, the graft layers cannot move relative to the stent structure in any direction. For example, with reference to Figure 2 of Kuwahara, if pressure is applied to the graft layer in an effort to move the graft layer toward the left side of the stent, the attached areas on the left side will restrain movement since the left attached areas are abutting against the left apices of the stent structure. Likewise, if pressure is applied to the graft layer in an effort to move the graft layer toward the right side of the stent, the attached areas on the right side will restrain movement since the right attached areas are abutting against the right apices of the stent structure. Thus, unlike the claimed invention, the unattached margins are not on the same side of the attached areas to allow the graft layers to move relative to the stent structure. Accordingly, Kuwahara does not disclose all of the limitations of claim 1. Therefore, claim 1 is allowable over Kuwahara.

Lentz also does not disclose all of the limitations of claim 1. Lentz discloses a plurality of ring stents positioned between an inner and outer graft layer. Each ring stent is disposed within a pocket formed between the graft layers. (Col. 5, lines 39-49). In contrast to Lentz, the claimed invention requires a unitary stent structure with radial openings. The radial openings are axially and circumferentially defined by the struts of the stent structure. The attached areas which are claimed in claim 1 are located within the defined radial openings and allow the graft layers to move relative to the stent structure. In Lentz, however, there is no unitary stent structure and no radial openings extending therethrough. In Lentz, the individual ring stents merely float within a corresponding pocket. However, in the invention claimed in claim 1, the graft layers can move relative to the entire length of the unitary stent structure. Accordingly, Lentz does not disclose all of the limitations of claim 1. Therefore, claim 1 is allowable over Lentz. In addition to limitations missing from Kuwahara and Lentz, the prior art of record fails to disclose the additional limitations of dependent claims 2-27. Because each of these claims incorporate all of the limitations of allowable claim 1, claims 2-27 are also allowable. Therefore, any further arguments that could be made at this time in support of the additional limitations of Applicants' dependent claims would be superfluous and unnecessary. *In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988); *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1555 (Fed. Cir. 1983).

Turning to claims 28-34, Applicants have amended independent claim 28 to further distinguish the claimed invention from the prior art. The Examiner has argued that it would have been obvious to combine Lentz and Buirge to achieve the invention of claim 28. However, there is no suggestion or motivation to combine Lentz and Buirge as the Examiner has done. Buirge discloses a stent with an inner and outer layer of SIS material. The entire assembly is immersed in water and then heated to bond the collagen layers together. ([¶¶ [0059] – [0060])). Thus, it is clear from Buirge that the stent is embedded within the SIS layers and there are no regions where the SIS layers are unattached. With respect to the inner and outer layers, Buirge and Lentz are unrelated to each other. Buirge involves graft layers that are made from natural tissues (SIS), whereas Lentz involves graft layers that are made from artificial materials (ePTFE and Dacron). Natural tissues and artificial materials have different characteristics and design considerations and are not easily substituted for one another. There is no teaching in the prior art of record that one of skill in the art would consider attaching inner and outer layers made of natural tissues to each other only at discrete areas of attachment. Buirge only teaches that a stent structure may be embedded in SIS material. However, this is the opposite of Applicant's claimed invention where only portions of the graft layers are attached to each other and unattached margins in which the graft layers are not attached to each other exist between the attached areas and the stent structure. Accordingly, Lentz and Buirge cannot be combined because there is no motivation or suggestion to combine Lentz and Buirge, either expressly or implicitly, in the cited prior art. *In re Kahn*, 441 F.3d 977, 987-88 (Fed. Cir. 2006); MPEP § 2143.01. Therefore, claim 28 is allowable. The prior art of record also fails to disclose the additional limitations of dependent claims 29-34. Because each of these claim incorporate all of the limitations of allowable claim 28, claims 29-34 are also allowable. Therefore, any further arguments that could be made at this time in support of the additional limitations of Applicants' dependent claims would be superfluous and unnecessary. *In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988); *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1555 (Fed. Cir. 1983).

Turning to claim 35, Applicant has incorporated the limitations of claims 1 and 5 into new claim 35. The Examiner has argued that Lentz discloses all of the limitations

of claim 5, which requires the first and second attached areas to be positioned adjacent edges of the stent structure to restrict movement of the graft layers in a second direction (now incorporated into claim 35). However, Applicant respectfully submits that Lentz does not disclose this limitation. With respect to claim 5, the Examiner has stated that Figure 3 of Lentz discloses all of the limitations of claim 5. However, as explained above, Lentz does not disclose the unitary stent structure as now recited in amended claim 1 and new claim 35. In addition, there is no disclosure in Lentz of two attached areas of the graft layers being located on opposite sides of radial openings in the stent structure to restrict movement of the graft layers in a second direction. An example of this embodiment is shown in Figure 3 of Applicant's application, which shows some of the attached areas 22 (for example in the center of the figure) located on opposite sides of the radial openings 16. As a result, in Figure 3, the graft layers may move axially relative to the stent structure, but the graft layers are restricted in the circumferential direction relative to the stent structure. (¶ [0021]). By contrast, Lentz discloses gaps on both sides of the attached areas and the ring stents. There is no disclosure in Lentz that the attached areas can be located adjacent an edge of a stent structure to restrict movement in one direction. Accordingly, Lentz does not disclose all of the limitations of claim 35. Therefore, claim 35 is allowable.

Turning to claim 36, Applicant has incorporated the limitation of claim 7 into new claim 36. The Examiner has argued that Lentz discloses all of the limitations of claim 7, which requires the unattached margins to extend peripherally all around the attached areas (now incorporated into claim 36). However, Applicant respectfully submits that Lentz does not disclose this limitation. With respect to claim 7, the Examiner has stated that Figure 3 of Lentz discloses all of the limitations of claim 7. An example of this embodiment is shown in Figure 1 of Applicant's application, which shows discrete attached areas 22 that are spaced away from all the edges of the radial openings, both forward and rearward in the axial direction and side-to-side in the circumferential direction. As a result, in Figure 1, the graft layers may move axially and circumferentially relative to the stent structure. (¶ [0020]). By contrast, Lentz discloses attached areas that wrap all the way around the circumference of the stent-graft. (Col. 5, lines 41-46). Thus, Lentz does not disclose discrete attached areas with unattached

margins extending peripherally all around the attached areas. Accordingly, Lentz does not disclose all of the limitations of claim 36. Therefore, claim 36 is allowable.

## **Conclusion**

In response to the Examiner's comments, Applicants have amended claims 1, 7 and 28 and added new claims 35-36. It is respectfully submitted that none of the prior art of record discloses all of the limitations of the claims as now presented.

Furthermore, there is no suggestion or motivation to combine the prior art to achieve Applicants' claimed inventions. Therefore, Applicants' claims are allowable.

Accordingly, Applicants request reconsideration and allowance of the application.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Richard E. Stanley, Jr.", is written over a horizontal line.

Richard E. Stanley, Jr.  
Registration No. 45,662  
Attorney for Applicants

BRINKS HOFER GILSON & LIONE  
P.O. BOX 10395  
CHICAGO, ILLINOIS 60610  
(312) 321-4200